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March 7, 2000

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2000 MAR -8 P 12:00

Via Facsimile

Vivian Gilliam
Division of Petition Control
Office of Pre-market Approval
Center for Food Safety and Applied Nutrition
Room 1144
Food and Drug Administration
1110 Vermont Avenue, NW
Washington, D.C. 20036

Re: **Great Lakes Chemical Corporation; Food Additive Petition No. 4B4418; Revised Environmental Assessment; Our File No. GR10705**

Dear Ms. Gilliam:

Following up on our recent telephone conference in which you requested that we provide the Agency with a completely revised Environmental Assessment (EA) for the above-referenced Food Additive Petition, we are enclosing a revised EA that you should find responsive to your request. The chemical description contained in the EA, including in section 4 ("Proposed Action") and in section 9 ("Use of Resources and Energy") has been updated to replace the name of the chemical substance as it will appear in the final regulation. In addition, we have added the date block to the certification page.

We trust this submission is fully responsive to your request, and now look forward to prompt publication of the final rule responsive to the petition. Should you have any further questions, however, please do not hesitate to contact us.

Sincerely yours,

George G. Misko

EA 1

GREAT LAKES CHEMICAL CORPORATION

FDA Food Additive Petition No. 4B4418

AMENDMENT

Section G - Environmental Assessment

FOR LISTING OF

1,3-dihalo-5,5-dimethylhydantoin
(where the dihalo (halogen) may
be bromine and/or chlorine)

in

Title 21 of the Code of Federal Regulations, Part 176-
Indirect Food Additives: Paper and Paperboard Components
Subpart B Section 176.300, Slimicides

Submitted By:

George G. Misko, Esq.
Counsel for Great Lakes Chemical Corporation
Keller and Heckman, LLP

For:

Great Lakes Chemical Corporation
West Lafayette, Indiana 47906

Date:

March 7, 2000

ENVIRONMENTAL ASSESSMENT
REVISION
(21 CFR 25.3 1a(b)(1))

The information is in the format for additives that are present in food packaging materials at not greater than 1.0 kg per 1000 kg dry weight of fiber and that are also non-functional components of food packaging materials.

1. March 7, 2000

2. Great Lakes Chemical Corporation
3. P.O. Box 2200
   One Great Lakes Boulevard
   West Lafayette, IN 47906

4. Proposed Action:

Great Lakes Chemical Corporation (GLCC) is requesting that Title 21 CFR 176.300 be amended to provide for the safe use of 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) (BCDMH) as a slimicide in the manufacture of paper and paperboard that contact food. This will permit use of a proven efficient slimicide that is effective at low concentrations and does not result in any significant impact on the environment.

BCDMH product intended for use as an approved slimicide is currently produced by GLCC at Adrian, Michigan. The plant site is located in an urban area industrial park. Adjacent to the GLCC plant are other specialty chemical manufacturers. The closest residential area is approximately three city blocks from the GLCC plant site.

The GLCC plant is permitted for several different types of waste disposal. All liquid process waste is disposed using deep-well injection. Only sanitary sewage is released to the city wastewater treatment facility. Volatile process emissions are vented through scrubbing systems at the GLCC facility resulting in environmental air emissions that are regulated and permitted by the Department of Natural Resources. Solid waste consisting of non-recoverable product and floor sweepings and disposed at the local land disposal facility according to established permit regulations.

BCDMH is approved for use by the Environmental Protection Agency (EPA) in a number of Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) registrations. The proposed action will possibly increase production levels by 5% (i.e., by about one million pounds per year). The product would be used in small amounts at a number of paper mills throughout the United States. These mills are currently subject to EPA and NPDES regulations.

Food-packaging materials will be used in patterns corresponding to the national population density and will be widely distributed across the country. Consequently, disposal will occur nationwide with the materials ultimately being deposited in landfills, incinerated, or recycled (where possible). Environments potentially affected by disposal would be watersheds or groundwater receiving leachate from land disposal sites and areas subject to air emissions from landfills and incineration sites.

In solution, after biological demand, BCDMH breaks down to form bromide ion, chloride ion, and dimethylhydantoin. At normal usage levels of BCDMH, free halogen ions are not released in quantities to warrant any environmental concern. DMH has no tendency to bioaccumulate and is considered harmless at these low levels. It is well known that DMH degrades rapidly in active biological systems. DMH is not detected in lab samples of paper sheet produced from a pulp mix containing up to 400 ppm of DMH. This data is also confirmed by others who report that the amount of residual DMH in recirculating cooling towers is considerably less than expected. In actual use, the maximum level of 5 ppm bromine would only be maintained during periods of excessive microbiological fouling. Environmental effect and fate results are summarized in the table presented on the following page (reference original FAP page 21 of 203).

End of Item No. 4.

5. Chemical Identity

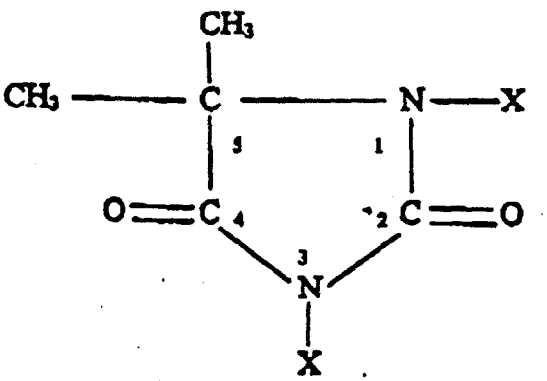
The chemical substance that is the subject of the proposed action is 1,3-Dihalo-5,5,-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine) (BCDMH). The additive may consist of any of the following compounds, alone or in combination:

Chemical Name	CAS Number	Molecular Formulation	Molecular Weight
1-bromo-3-chloro-5,5-dimethylhydantoin	CAS No. (16079-88-2)	$C_5H_6N_2O_2BrCl$	241.47
3-bromo-1-chloro-5,5-dimethylhydantoin	CAS No. (126-06-7)	$C_5H_6N_2O_2BrCl$	241.47
1,3-dibromo-5,5,-dimethylhydantoin	CAS No. (77-48-5)	$C_5H_6N_2O_2Br_2$	285.92
1,3-dichloro-5,5,-dimethylhydantoin	CAS No. (118-52-5)	$C_5H_6N_2O_2Cl_2$	197.02

The product exists in aqueous solution as dimethylhydantoin, the halogen atoms being released in solution to yield hypochlorous acid and hypobromous acid, the active ingredients. Thus, to the extent the additive is incorporated into the paper and may be ingested in food, it will be in the form of dimethylhydantoin regardless of the specific composition of the dihalogenated product.

BCDMH is an antimicrobial pesticide registered under FIFRA as 1-bromo-3-chloro-5,5-dimethylhydantoin. BCDMH is a stable powder in the dry form. The BCDMH product also contains by-product sodium chloride and water. Sodium carbonate (CAS No. 497-19-8) may also be present as an additive in BCDMH.

The structural formula for BCDMH is:



Where X=Br or Cl

6. Introduction of Substances Into The Environment

GLCC's Adrian, Michigan facility complies with all applicable emission and occupational Federal, State, and Local laws and regulations. All liquid waste is deep-well injected according to state regulations. The deep-well injection UIC permit number is MI-091-1I-0001, expiration date, April 19, 1999. Only sanitary sewage is released to the city wastewater treatment facility. Air emissions at the GLCC facility are permitted by the Department of Natural Resources. The Air Permit application, number 309-92, has been submitted to the State of Michigan and is pending approval. Solid waste, which consists of non-recoverable product and floor sweepings, is regulated by the local land disposal facility. The land disposal permit number is MID-081-213027. The requested approval will have no effect on compliance with current emission requirements at this production site.

The manufacture of the product involves the use of dimethylhydantoin, bromine, chlorine, and sodium hydroxide resulting in the formation of BCDMH, plus sodium chloride, and water. Substances expected to be emitted to the environment are bromine, chlorine, ammonia, particulate, trace level trimethylamine, and trace level hydrogen cyanide. Abatement systems used to control emissions at the Adrian GLCC facility consist of caustic and acid scrubbers. The dimethylhydantoin (DMH) process emits ammonia, trace (ppb) level trimethylamine and trade (ppb) level hydrogen cyanide. Emissions are vented through a two stage abatement system consisting of first a caustic scrubber, then an acid scrubber. This treatment reduces the emissions to the permitted concentrations. The BCDMH process emits bromine and chlorine which are vented through a caustic scrubber reducing emissions to the permitted concentrations. Particulate is produced during the drying process. HEPA filters are used to remove particulate matter to a level that complies with permitted concentrations.

The estimated added annual volume would be about 5% of current production or about one million pounds. The material would be used in widely dispersed areas. Paper mills normally average 40-60% water content in the paper when it goes into the dryer. Treatment level in the white water loop is recommended up to 5 ppm as bromine. At the maximum use level of 5 ppm bromine in a papermill having no halogen demand, an estimated 2 ppm DMH residual will end up in the white water. Because of concentration on drying (60% water maximum), paper from this system could contain up to 2.7 ppm DMH. Although this level is within the limit of detection, spiking studies in our laboratory show this amount to be undetectable on paper formed from an equal mixture of hard and soft wood pulp, see Enclosure A, Part 7. This is not unexpected, since an independent testing laboratory in Germany has shown that when a pulp slurry is spiked with up to 400 ppm of BCDMH, no DMH was detected in the paper produced. The results of this experiment was the basis of Great Lakes Chemical Corporation obtaining approval to allow the use of BCDMH as a slimicide in the manufacture of food contact paper in Europe. Additional details are in Enclosure A, Part 7.

BCDMH is widely used as a microbiocide in such diverse areas as industrial water treatment, recreational water treatment and the protection of water used in the irrigation of ornamental plants.

GLCC or wholly owned subsidiaries hold EPA FIFRA registration approvals under the following titles:

EPA No.	PRODUCT NAME	APPROVED USES
5785-57	BromiCide®	Algicide, bactericide and slimicide in recirculating cooling water systems and once-through cooling towers.
5785-65	BromiCide® Granules	Disinfectant, sanitizer bactericide, slimicide and algicide in cooling or retort water; in the poultry or meat inspection programs; brewery pasteurizers; once-through industrial cooling water systems; and primary, secondary, and tertiary wastewater treatment systems.
5785-63	BromiCide® Tablets	Disinfectant, sanitizer, bactericide, slimicide and algicide in cooling and retort water; in boiler, steam lines and cooling systems in the meat, poultry and egg inspection program; in recirculating cooling water systems; once-through cooling water systems; evaporative coolers; commercial air conditioner and dehumidifiers basins or drip pans; and wastewater treatment systems.
5785-69	AgriBrom® Tablets	Antimicrobial and fouling in recirculating cooling water, irrigation and automatic water distribution systems in greenhouses.
5785-70	Agribrom® Granules	For control of microbial slimes and fouling in recirculating cooling water, irrigation and automatic water distribution systems in greenhouses.
5785-100	501 BT	For use as a disinfectant, sanitizer, bactericide, slimicide and algicide in recirculating cooling water systems; brewery pasteurization systems; evaporative coolers; and commercial air conditioner and dehumidifier basins or drip pans.

MSDSs for all substances that workers are exposed to at the Adrian plant site are

provided in Appendix I.

7. Fate of Emitted Substances in the Environment:

BCDMH hydrolyzes in water to form hypobromous acid, hypochlorous acid, and DMH. The physical properties are given in the identity section of the petition. At the maximum measured usage level of 5 ppm bromine, complete hydrolysis could result in a residual of 2 ppm of DMH. At 80% recycle this means 0.4 ppm of DMH could be released to the environment. This amount would be greatly reduced to undetectable levels by the large dilution in a papermill.

In solution, after biological demand, BCDMH breaks down to form bromide ion, chloride ion, and dimethylhydantoin. At normal usage levels of BCDMH, free halogen ions are not released in quantities to warrant any environmental concern. DMH has no tendency to bioaccumulate and is considered harmless at these low levels. It is well known that DMH degrades rapidly in active biological systems. DMH is not detected in lab samples of paper sheet produced from a pulp mix containing up to 400 ppm of DMH. This data is also confirmed by others who report that the amount of residual DMH is recirculating cooling towers is considerably less than expected. In actual use, the maximum level of 5 ppm bromine would only be maintained during periods of excessive microbiological fouling. Environmental effect and fate results are summarized in the table presented on the following page (reference original FAP page 21 of 203).

8. Environmental Effects of Released Substances:

Dimethylhydantoin, the carrier molecule, has been thoroughly tested and its impact on the environment indicates no area of concern. DMH is relatively stable in water with a half-life in excess of 182 days. DMH has not shown any tendency to bioaccumulate in terrestrial or aquatic species and rapidly degrades to CO_2 in activated sludge. When BCDMH is used as a slimicide (especially at alkaline pH), it is expected that, because of the increased activity of bromine over chlorine, less active halogen would be required. Therefore, less BCDMH will be discharged.

Bromine compounds decompose more quickly than chlorine based biocides and are therefore less harmful to the environment. The faster decomposition rate is in part due to the lower carbon to bromine bond energy of 70 kcal/mole compared to a carbon to chlorine bond energy of 84 kcal/mole. The environmental effect data are reported beginning on page 007230 of Master File No. 522. These results are summarized in the table on the following page (reference original FAP page 21 of 203). A copy of the index for Master File No. 522 is attached for your reference as Enclosure C.

9. Use of Resources and Energy:

The slimicide BCDMH is intended to replace equivalent alternative chlorine based oxidizing biocides. The approval of BCDMH will not materially change the uses of the packaging materials into which it is incorporated. The proposed slimicide, 1,3-dihalo-5,5-dimethylhydantoin (where the dihalo (halogen) may be bromine and/or chlorine), is intended as a

competitive alternative to other slimicides already in use and will not materially change the total amount of energy or resources required. The approval of BCDMH as a slimicide will have no adverse effect on endangered or threatened species.

10. Mitigation Measures

No adverse environmental effects are anticipated with the use of BCDMH as a slimicide in paper making. No mitigating measures are necessary.

11. Alternatives to the Proposed Action

No adverse environmental effects have been identified. No alternatives are required.

Summary of
Environmental Data Results For Dimethylhydantoin (DMH)

	Study	Result
1.	Hydrolysis of ^{14}C Dimethylhydantoin	Minimal hydrolysis with a half-life of 182 days at pH9
2.A*	Aquatic static bioassays of DMH toxicity to sheepshead minnows, grass shrimp and oysters.	Not toxic - 12,700 to 14,200 mg/L
2.B*	Aquatic static bioassay of DMH to water flea	1,300 to 8,100 mg/L
2.C	LC_{50} values (reference page 4940 of FMF No. 522) for 5,5-dimethylhydantoin for individual species are:	

Organism	LC_{50} value (mg/L)
Grass shrimp (M)[1]	1,300
Water flea (FW)[2]	6,100
Sheepshead minnow (M)	8,100
Rainbow trout (FM)	12,700
American oyster (M)	13,300
Fathead minnow (FW)	14,200

[1] (M) refers to Marine organisms
[2] (FW) refers to Fresh Water organisms

3.	Aquatic dynamic bioconcentration study on bluegill and sunfish.	No bioconcentration in 28 days
4.	Aerobic aquatic metabolism of DMH	No degradation products found
5.	Aerobic soil metabolism (1 year study)	No degradation

	Study	Result
6.	Anaerobic aquatic metabolism (^{14}CDMH)	No change
7.	Soil/sediment adsorption/desorption of DMH.	No significant adsorption on test soils
8.	Leaching characteristics.	Majority recovered in leachate
9.	Photodegradation of DMH.	Minimal - half-life, 2,400 days
10.	Octanol - water partition coefficient	0.35
11.	Biodegradation of DMH in activated sludge	Degrades rapidly to CO_2 in activated with no toxic effects observed
12.	COD of DMH	1,005 mg O_2/gr DMH
13.	BOD of DMH	Negligible

* Also includes studies on bromochloro-5,5-dimethylhydantoin.

12. List of Preparers:

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See Appendix II for Preparer's credentials and qualifications.

13. Certification:

The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of the firm or agency responsible for the preparation of the environmental assessment.

3-7-00
Date

George G. Misko, Esquire
Counsel for Great Lakes Chemical Corporation
Keller and Heckman LLP